IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

IN RE: DEPUY ORTHOPAEDICS, INC. PINNACLE HIP IMPLANT PRODUCTS LIABILITY LITIGATION	§	MDL Docket No. 3:11-MD-2244-K
This Order Relates To:	§	
Lay v. DePuy Orthopaedics, Inc., et al. No. 3:11-cv-03590-K	§	
Herlihy-Paoli v. DePuy Orthopaedics, Inc., et al. No 3:12-cv-04975-K	§	

MEMORANDUM OPINION AND ORDER DENYING DEFENDANT DEPUY ORTHOPAEDICS, INC.'S MOTIONS TO EXCLUDE EXPERT TESTIMONY

Before the Court are six motions of Defendant DePuy Orthopaedic, Inc. ("DePuy") to exclude expert testimony in *Lay v. DePuy Orthopaedics, Inc., et al.*; No. 3:11-cv-03590-K ("Lay") and *Herlihy-Paoli v. DePuy Orthopaedics, Inc., et al.*; No. 3:12-cv-04975-K ("Paoli"). For the reasons set forth herein, the motions are DENIED.

DePuy moves to exclude the testimony of the following Plaintiffs' experts in the *Lay* and *Paoli* cases:

1. John Abramson, M.D. [Lay Dkt. No. 25; Paoli Dkt. No. 22];

2. Scott Bayley, C.P.A. [Lay Dkt. No. 29; Paoli Dkt. No. 20];

3. Rudolph Buchheit, Ph.D. [Lay Dkt. No. 33; Paoli Dkt. No. 30];

4. Vicki Colvin, Ph.D. [Lay Dkt. No. 31; Paoli Dkt. No. 28];

5. Nicholas Jewell, Ph.D. [Lay Dkt. No. 27; Paoli Dkt. No. 24]; and

6. John Ziegert, Ph.D. [Lay Dkt. No. 35; Paoli Dkt. No. 26].

I. PROCEDURAL AND FACTUAL BACKGROUND

Pursuant to 28 U.S.C.§1407, the United States Judicial Panel on Multidistrict Litigation ordered coordinated or consolidated pretrial proceedings in this Court of all actions involving the Pinnacle Acetabular Cup System hip implants ("Pinnacle Device") manufactured by DePuy. The DePuy Pinnacle multidistrict litigation ("MDL") involves DePuy's design, development, manufacture, and distribution of the Pinnacle Device. The Pinnacle Device is used to replace diseased hip joints and was intended to remedy conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis, or fracture, and to provide patients with pain-free natural motion over a longer period of time than other hip replacement devices.

Presently there are over six thousand cases in this MDL involving Pinnacle Devices made with sockets lined with metal, ceramic, or polyethylene. The Plaintiffs in the MDL act through a large group of Plaintiffs' lawyers that form the Plaintiffs' Steering Committee ("PSC"). The PSC is headed by the Plaintiffs' Executive Counsel ("PEC"), a small group from the PSC appointed by this Court to conduct discovery and other pretrial proceedings and identify common issues in the MDL. At the Court's direction, the PEC and the Defendants have identified eight bellwether cases and, from

the group, have chosen *Lay* and *Paoli* to be the first two of the bellwether cases to be called for trial on September 1, 2014.

A. The PEC's Allegations

The PEC's basic theory of liability focuses on the differences between the body's reaction to the different wear debris generated by different types of hip implants. In the *Lay* and *Paoli* cases, the PEC alleges that in the metal-on-metal design of the Pinnacle Device, wear of the articulating surfaces can produce metallic ion debris (cobalt and chromium) within the periprosthetic space and that the body can have a significant inflammatory response to metal debris that can lead to periprosthetic bone and/or tissue necrosis, resulting in the need for revision surgery.

Modern total hip arthroplasty involves removing a diseased hip joint and replacing it with an implant. In general, a modular hip implant incorporates both a femoral and acetabular component. The femoral portion requires a metal stem to be placed in the center of the femur with a metal ball replacing the femoral head. The acetabular component consists of a metal cup that replaces the acetabular socket and holds a liner that can be made of either metal, ceramic, or polyethylene. Metal-on-metal articulation refers to a total hip arthroplasty in which a metal femoral head articulates with a metal acetabular cup liner. Particles of various sizes and shapes (including nanoparticles) wear away from all types of hip components. The body's immune system can respond differently to different types of wear particles. The Pinnacle Devices in the *Lay* and *Paoli* cases are metal-on-metal, *i.e.*, they have sockets lined with metal.

B. Allegations Specific to *Lay*

On or about September 11, 2006, Mrs. Lay underwent a right total hip arthroplasty with a DePuy Pinnacle metal-on-metal hip. On or about April 16, 2007, Mrs. Lay, underwent a left total hip arthoplasty with a DePuy Pinnacle metal-on-metal hip. Dr. Allmacher performed both of Mrs. Lay's surgeries in Missoula, Montana.

In June of 2010, diagnostic tests revealed the presence of cobalt and chromium in Mrs. Lay's blood system and an amorphous fluid consistent with metallosis located in the vicinity of her left hip. From these findings, Dr. Allmacher concluded that the left Pinnacle hip had failed. On or about June 30, 2010, Mrs. Lay underwent revision surgery of her left implant during which a collection of fluid consistent with metallosis and significant soft tissue necrosis of the gluteus medius muscle was discovered. Mrs. Lay now lacks effective muscular control in her left hip and cannot ambulate normally without assistance.

After the left hip revision surgery, Mrs. Lay experienced increased pain in her right hip which required additional testing. From the testing, Dr. Allmacher determined that her right hip had also failed. On or about December 27, 2010, Mrs. Lay underwent surgery to remove the right hip arthoplasty. Dr. Allmacher evacuated large amounts of fluid and the proximal femur showed fibrous tissue consistent with chronic inflammation. A sinus of approximately .5 cm of the posterior soft tissues was not intact and there was also corrosion at the Morse taper junction.

The extensive damage to Mrs. Lay's left hip required a second revision surgery on April 27, 2011. During this surgery, Dr. Allmacher observed that approximately 50% of the gluteus medias tendon inserted posteriorly and the posterior capsule of the hip were deficient. On June 28, 2011, Mrs. Lay underwent additional surgery for the total extraction of her left total hip, which had become infected, and for placement of an antibiotic spacer. The physician evacuated a large amount of infected fluid and observed significant soft tissue necrosis throughout the hip. Mrs. Lay's soft tissue continued to have a black/grey color consistent with muscle death from metallosis. The most significant necrosis was in the areas of the gluteus medius and gluteus minimus muscles. There was also necrosis present in the proximal aspect of the vastuslateralis fascia.

Again, on or about July 20, 2011, Mrs. Lay underwent surgery for a repeat incision and drainage of the left total hip arthroplasty and antibiotic bead placement. Dr. Allmacher identified a large hematoma/seroma and evacuated fluid. On or about May 2, 2012, Mrs. Lay underwent another surgery for a repeat incision and drainage of the left total him arthroplasty. All trial components were removed, and Mrs. Lay was fitted with final hip implants.

C. Allegations Specific to *Paoli*

On or about October 19, 2009, Mrs. Paoli underwent a right total hip arthroplasty with a DePuy Pinnacle metal-on-metal hip. On or about December 14, 2009, Mrs. Paoli, underwent a left total hip arthoplasty with a DePuy Pinnacle metal-

on-metal hip. Dr. Allmacher performed both of Mrs. Paoli's surgeries in Missoula, Montana.

After her surgeries, Mrs. Paoli began to experience severe pain in her hip and thigh. Mrs. Paoli reported her experiences to Dr. Allmacher, and Dr. Allmacher determined the implants had released dangerous levels of cobalt and chromium into her blood stream. Dr. Allmacher notified Mrs. Paoli that she required a revision surgery. In preparation for the revision surgery, Dr. Allmacher suggested that Mrs. Paoli's cobalt and chromium levels be tested. The test indicated that Mrs. Paoli's cobalt blood serum levels were 85 times higher than normal. Further, an MRI showed a sizable mass surrounding the left implant.

On April 26, 2011, Dr. Henrick Malchau performed a total hip revision surgery on Mrs. Paoli's left hip. Dr. Malchau noted cloudy synovial fluid inside Mrs. Paoli's hip and confirmed that the left implant had failed. Dr. Malachau further discovered the implant had turned black from metallosis. On or about November 8, 2011, Mrs. Paoli underwent an additional surgery to remove her right Pinnacle implant which was also performed by Dr. Malchau.

II. BURDEN OF PROOF FOR EXCLUSION OF EXPERT TESTIMONY

For years, the admission of expert testimony in Federal Court was governed by the common law *Frye* test, named for the 1923 appellate case that first expressed the notion that expert scientific evidence was admissible only if it was based upon scientific principles that had met "general acceptance." *Frye v. United States,* 293 F. 1013 (D.C.

Cir. 1923). In 1973, the Federal Rules of Evidence replaced the *Frye* test by removing some of the restrictions on expert testimony. Federal Rule of Evidence 702 governs the admissibility of expert testimony and omits the "general acceptance" language of *Frye.* Instead, rule 702 provides that: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." FED. R. EVID. 702. The Supreme Court affirmed that rule 702 replaced the *Frye* test and stated that the dual standards of "relevance" and "reliability" would determine the admissibility of expert testimony. *Daubert v. Merrell Dow Pharms., Inc.,* 509 U.S. 579, 589 (1993). Rule 702 was amended in 2000 and now provides more guidance, instructing that the Court should assist the trier of fact by admitting expert evidence "if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." FED. R. EVID. 702.

Faced with a proffer of expert scientific testimony, this Court must determine at the outset admissibility under rule 702 by following the directions provided in rule 104(a) of the Federal Rules of Civil Procedure. Under rule 104(a), this Court is to conduct preliminary fact finding and to make a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and whether

that reasoning or methodology properly can be applied to the facts of the case. FED. R. EVID. 104(a); *Daubert,* 509 U.S. at 592-93. This Court, however, is not bound by the rules of evidence in determining preliminary questions concerning qualification of witnesses and admissibility of evidence. FED. R. CIV. P. 104(a); *Moore v. Ashland Chemical Inc.*, 151 F.3d 269, 276 (5th Cir. 1998). The party offering expert testimony has the burden to prove by a preponderance of the evidence that the testimony satisfies rule 702. *Mathis v. Exxon Corp.,* 302 F.3d 448, 459-60 (5th Cir. 2002). This Court has broad discretion in determining the admissibility of expert evidence under *Daubert. Knight v. Kirby Inland Marine Inc.,* 482 F.3d 347, 351 (5th Cir. 2007). Once it is determined that an expert is qualified to testify, the proponent need only demonstrate that the expert's findings and conclusions are more likely than not reliable. *Moore,* 151 F.3d at 276.

The expert's opinions do not have to be either infallible or uncontradicted to be admissible; the question of whether the expert's opinions are correct is reserved for the fact finder. *Wattle v. Barko Hydraulics LLC*, 107 Fed. Appx. 396, 398 (5th Cir. 2004). *Daubert* makes clear that the appropriate means of attacking admissible, albeit shaky, evidence is through vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof. *Daubert*, 509 U.S. at 596*; see also Primrose Operating Co. v. National American Insurance Co.*, 382 F.3d 546, 562 (5th Cir. 2004) ("It is the role of the adversarial system, not the court, to highlight weak evidence . . .").

A. The Qualification Requirement

The first key to the admission of expert testimony is an expert who is qualified to testify on the subject at issue. A witness testifying under rule 702 must be qualified as an expert by "knowledge, skill, experience, training, or education." FED. R. EVID. 702. The witness's qualification as an expert may be by way of education, even in the absence of practical, hands-on experience. *Lavespere v. Niagara Machine & Tool Works, Inc.,* 910 F.2d 167, 176-77 (5th Cir. 1990), *cert. denied,* 510 U.S. 859 (1993). A formal education, however, is not required; practical experience may suffice. *United States v. Hernandez-Palacios,* 838 F.2d 1346, 1350 (5th Cir. 1988).

B. The Reliability Requirement

In *Daubert,* the Supreme Court provided a list of four non-exhaustive factors that a court may use in making its gatekeeping determination of reliability: (1) "whether a theory or technique. . . can be (and has been) tested," (2) "whether the theory or technique has been subjected to peer review and publications," (3) whether, "in the case of a particular scientific technique," there is a high "known potential rate of error" and there are "standards controlling the technique's operation," and (4) whether the theory or technique enjoys "general acceptance" within a "relevant scientific community." *Daubert,* 509 U.S. at 593-94. The *Daubert* factors, however, are not definitive or exhaustive. *Broussard v. State Farm Fire & Casualty Co.*, 523 F.3d 618, 631 (5th Cir. 2008) (data from space center and eyewitnesses relied upon to form opinion was

sufficiently reliable and expert opinion admissible despite the fact "his work had not been peer reviewed and he did not know of others who had used his methods"); *see also In re Vioxx Products Liability Litigation,* No. 05-4046, 2006 WL 6624015 at *4 (E.D. La. Feb. 3, 2006) ("Whether some or all of [the *Daubert*] factors apply in a particular case depends on the facts, the expert's particular expertise, and the subject of his testimony.") (*citing Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 138 (1999)).

C. The Relevance Requirement

In addition to determining whether the proffered expert testimony is reliable, the Federal Rules of Evidence and the Supreme Court require that this Court determine whether the evidence will assist the trier of fact—the relevance requirement. Rule 402 provides that all relevant evidence is admissible unless otherwise provided. FED. R. EVID. 402. Relevant evidence is defined as that which has any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence. FED. R. EVID. 401; *Daubert,* 509 U.S. at 587. The *Daubert* court provides this example of relevance:

> The study of the phases of the moon, for example, may provide valid scientific "knowledge" about whether a certain night was dark, and if darkness is a fact in issue, the knowledge will assist the trier of fact. However (absent credible grounds supporting such a link), evidence that the moon was full on a certain night will not assist the trier of fact in determining whether an individual was unusually likely to have behaved irrationally on that night. *Id*. at 591.

III. ANALYSIS

Daubert and rule 702 are not intended to provide an automatic challenge to the testimony of every expert; rather, the rejection of expert testimony is the exception not the rule. FED. R. EVID. 702 advisory committee note (2000). A review of cases within the Fifth Circuit in which expert opinions have been deemed unreliable and inadmissible reveals extreme circumstances of unreliability that were well beyond, for example, whether the expert considered all potentially relevant literature. *See Burleson v. Glass*, 268 F. Supp. 2d 699, 704-05 (W.D. Tex. 2003) (not one epidemiological study supported expert's theory, no published peer reviewed literature, and expert testified to "significant level of uncertainty" related to potential error in theory); *Frischhertz v. SmithKline Beecham Corp.,* No. 10-2125, 2012 WL 6697124 at *3-4 (E.D. La. Dec. 21, 2012) (general and specific causation opinions excluded as "pure speculation;" expert admitted that "he knew of no evidence in humans or animals that demonstrates that [drug] was . . . [a] teratogen, and that he does not know if it is. . ."); *Viterbo v. Dow Chemical Co.*, 826 F.2d. 420, 423-24 (5th Cir. 1987) (excluding expert after determining that the medical history that expert relied upon was incomplete in multiple respects).

A. The Expert Testimony of John Abramson

Plaintiffs offer Dr. Abramson as a designated expert on the truth of DePuy's marketing; DePuy's failure to disclose information in its possession about complications with Pinnacle Devices; DePuy's use of marketing to distribute messages about the

Pinnacle Device that were not supported by the data in DePuy's possession; and how DePuy disguised its marketing messages through the use of key opinion leaders and sponsored continuing medical education, programs, research, publications, and other similar techniques. Specifically, DePuy seeks to exclude the following opinions of Dr. Abramson in the *Lay* and *Paoli* cases:

1. DePuy falsely claimed the 99.9% five-year survivorship of Pinnacle Devices.
2. DePuy falsely claimed that Pinnacle Devices operate under true or full fluid lubrication.
3. DePuy falsely claimed that the Pinnacle Device produced the lowest published ion levels of any hip implants on the market.
4. DePuy's claim that run-in wear in the Pinnacle Device was reduced by 92% was misleading.
5. DePuy minimized the clinical importance of taper corrosion in its communications with surgeons, patients, and regulators.
6. DePuy paid physician consultants millions of dollars in return for input into the design and marketing of the metal-on-metal Pinnacle Devices.

DePuy contends that Dr. Abramson's testimony regarding these matters is inadmissible because Dr. Abramson, who is a family practitioner, is not qualified to give opinions about orthopedics and because his "opinions" are not really opinions but merely lengthy narratives and subjective interpretations of DePuy's documents and speculation of DePuy's state of mind, knowledge, and intent. In addition, DePuy contends that Dr. Abramson's opinions about DePuy's marketing efforts are not relevant.

Dr. Abramson's Qualifications

Dr. Abramson is a medical doctor trained in family practice; he does not specialize in orthopedic medicine. Plaintiffs, however, are not asking him to give opinions on orthopedic issues. Dr. Abramson's opinions involve analyzing scientific data and studies and comparing them to DePuy's marketing efforts. Dr. Abramson offers opinions about the truth of DePuy's marketing and about its failure to disclose information in its possession concerning complications with the Pinnacle Device. His opinions and report explain how DePuy used its marketing to communicate messages about the Pinnacle Device that were not supported by the data and how DePuy disguised marketing messages through the use of key opinion leaders and sponsorship of continuing medical education and other programs, research, and publications. Dr. Abramson is more than qualified to give these opinions.

Dr. Abramson completed his undergraduate work at Harvard College and obtained his medical degree from Brown Medical School in 1976. Dr. Abramson received training in epidemiology, statistics, research design, health policy, and interpretation of scientific data during his fellowship at Case Western Reserve University between 1980 and 1982. While his practice involved family medicine and he held several chair positions at various medical schools in that field, he also was a senior research associate on the faculty at the Institute of Health Policy at Brandeis University. In 1997, he was appointed a clinical instructor at Harvard Medical School, and in 2009,

he was appointed lecturer in Harvard's Department of Health Care Policy. While at Harvard, he taught and lectured extensively on the challenge to clinicians in trying to make informed decisions about pharmacotherapy care and how to interpret and integrate medical literature and data into a risk/benefit analysis in choosing appropriate treatments for patients. He has written extensively about the integrity of information that doctors rely upon in making clinical decisions. In 2002 he left his clinical practice to conduct full-time research in this area and has written a book on this issue. Dr. Abramson lectures extensively on the growing commercial influence on the production and dissemination of medical information available to those in the medical field.

Dr. Abramson's opinions about DePuy's marketing involve a comparison of DePuy's marketing messages and what the he opines the underlying scientific research actually showed. He is more than qualified to make this comparison due to his expertise in the area of the influence of marketing on medical decisions and also because of his specific training and expertise in research design and the interpretation of scientific data. His testimony is helpful to the fact finder (even an orthopedic surgeon) because he is interpreting complex scientific data to assess the truth of DePuy's marketing claims.

In forming his first opinion concerning the 99.9% five-year survivorship rate of the Pinnacle Device, Dr. Abramson analyzed the actual study on which DePuy claimed to rely as well as the marketing materials that made the survivorship claim to determine that DePuy has misrepresented the 99.9% figure. His second opinion concerning the

fluid film lubrication was formed in the same manner—by reviewing the study on which DePuy based its claims of fluid film lubrication and determining that DePuy's marketing claim of fluid film lubrication was false based on the study. Similarly, after reviewing the evidence of ion levels and run-in wear on the Pinnacle Device, he also concluded that DePuy's claims in this area were false and misleading.

With respect to his opinion about taper corrosion, he compared DePuy's internal documents to what it told surgeons, patients, and regulators and determined that DePuy failed to disclose to anyone problems with the Pinnacle Device that DePuy's own documents recognized. With respect to Dr. Abramson's opinions about payments to doctors, his expertise in healthcare marketing certainly qualifies him to opine that consultants were being paid not merely to help design the Pinnacle Device but also to help market the devices to other doctors.

DePuy's Claim that Dr. Abramson's Report Contains Inadmissible Speculation and Narrative

DePuy argues that Dr. Abramson's report is full of speculation about DePuy's intent and state of mind and narrative instead of opinion. What Dr. Abramson did was to review the data and studies and other information available to DePuy that formed the basis of DePuy's marketing claims and compare them to the claims actually made to conclude whether such claims were accurate. Dr. Abramson expresses no opinion on DePuy's intent or state of mind.

Dr. Abramson's report contains narrative summaries in addition to his opinions. Rule 26 of the Federal Rules of Civil Procedure requires an expert to include in his report a statement of all his opinions and the basis and reasons for them. FED. R. CIV. P. 26(a)(2)(B)(i). In addition, the expert is required to explain the facts or data considered in forming his opinions. FED. R. CIV. P. 26(a)(2)(B)(ii). Dr. Abramson complies with rule 26 in narrative form, summarizing the scientific studies and other facts relied on to reach his conclusions. Expert narrative testimony is entirely permissible where the documents and other information the expert is reviewing are complicated, voluminous, or involve scientific or technical data and such narrative summary would assist the trier of fact in understanding the documents. FED. R. EVID. 1006; *United States v. Osum,* 943 F.2d 1394, 1405 (5th Cir. 1991); *United States v. Pree,* 408 F.3d 855, 869-70 (7th Cir. 2005); *In re Welding Fume Products Liability Litigation,* No. 03-17000, 2005 WL 1868046 at *17 (N.D. Ohio Aug. 8, 2005).

The admission of Dr. Abramson's alleged speculation and narrative testimony, however, is not properly the subject of this Court's gatekeeping function under *Daubert.* It implicates this Court's discretion over the presentation of evidence at trial and should be taken up there. Recently, another court confronted with the same question about Dr. Abramson's narrative summary in a motion to exclude concluded that such matters should be decided at trial, and if the narrative testimony was admitted, defendant would have the opportunity during cross examination or the presentation of their own evidence

to address any issues. *In re Yasmin & YAZ (Drospirenone) Marketing, Sales Practices & Products Liability Litigation*, No. 09-02100, 2011 WL 6302287 at *8 (E.D. Ill. Dec. 16, 2011).

Relevance of Marketing Opinions

Dr. Abramson's report contains information regarding how DePuy conveyed marketing messages to doctors in many ways, not just through advertising: (1) DePuy paid consultant doctors not only to design the Pinnacle Device but also to market it to the medical community by participating in teleconferences, sales training sessions, and hosting surgeons for operating room observations; (2) DePuy used consultant key opinion leaders as the orthopedic equivalent to celebrity endorsers; (3) consultants spoke at conferences and published articles in national journals; (4) DePuy paid for studies to be published in medical journals; (5) DePuy sponsored continuing medical education programs and surgeon speaking groups where speakers were DePuy paid consultants. Dr. Abramson is qualified to form opinions about the effects of these marketing efforts on doctors and that doctors are generally not aware of the extent to which they are being influenced.

DePuy argues that Dr. Abramson's marketing opinions are not relevant in the *Lay* and *Paoli* cases because Dr. Allmacher testified that he did not rely on any of DePuy's advertising in deciding to use the Pinnacle Device. Dr. Allmacher did, however, have regular discussions with his DePuy representative, listened to key opinion leaders,

attended surgeon dinners and continuing medical education seminars, and read presentations and studies in medical journals regarding the Pinnacle Device. As Dr, Abramson opines, DePuy's marketing messages were conveyed to Dr. Allmacher and others through these activities even if Dr. Allmacher never reviewed any advertising materials from DePuy. Dr. Abramson's testimony is relevant.

B. The Expert Testimony of Scott Bayley

Plaintiffs offer Scott Bayley, C.P.A. as a designated expert to provide financial information and expertise about Defendants that would be useful to the trier of fact in determining punitive damages and to provide a detailed description of methodologies employed in evaluating such information. Mr. Bayley's report provides information about DePuy's financial condition and net worth and its ability to pay. Specifically, Mr. Bayley makes the following calculations:

1. A cash flow/dividend measurement which uses the amount of dividends that have been paid as a proxy for an amount that a company can pay without it causing appreciable harm to the business;
2. A materiality measurement in which a quantification of what might be considered a material misstatement for the purpose of financial reporting may be used as a proxy for what amount would have a material impact on a company's business; and
3. A credit rating measurement to measure the amount of payment that would cause a change in credit rating or outlook.

Bayley's calculations under these measurements range from $228 million to $5.78 billion.

DePuy contends that Mr. Bayley is being offered as an expert on the calculation of punitive damages and that Mr. Bayley's testimony regarding these matters is inadmissible because Mr. Bayley's opinions invade the province of the jury to determine the amount of punitive damages. DePuy argues that Bayley's calculations in essence provide the jury with a range of figures for a punitive damages award. DePuy also argues that such opinions are not based on reliable methodology for calculating punitive damages and are, therefore, unreliable.

Punitive Damages

Mr. Bayley is not being offered as an expert on punitive damages. He is a C.P.A. with expertise in evaluating businesses who has provided information about Defendants' financial condition, net worth, and ability to pay. Under Montana law, the controlling law in *Lay* and *Paoli*, a jury considering an award for punitive damages must consider the defendant's financial affairs, financial condition, and net worth. MONT. REV. CODE ANN. §27-1-221(7)(a). Punitive damages when awarded should be of a significant amount so as to deter by punishing the defendant and to warn others. *Gibson v. Western Fire Insurance Co.,* 682 P.2d 725, 740 (Mont. 1984). This may include consideration of the defendant's ability to pay. *See Johnson v. Horn,* 283 P. 427, 429 (Mont. 1929) (wealth and pecuniary ability of the defendant may be considered for punitive damages).

Mr. Bayley's report provides this information. He analyzes the financial condition and net worth of Defendants and using three different methods calculates Defendants'

ability to pay—information not within the general knowledge of the factfinder. He is not offering an opinion as to the amount of punitive damages that should be awarded; his opinion is the amount that Defendants could afford to pay before being adversely affected. Bayley calculates three different figures under the three methods for determining ability to pay. DePuy argues that Bayley is in essence providing a range of damages for the jury to award. That is not what Mr. Bayley is opining. He is giving the jury figures for Defendants' ability to pay—one of the statutory mandated factors to be considered in determining an amount of punitive damages. Again, DePuy's argument is not based on qualifications, relevance, or reliability. The admissibility of Mr. Bayley's testimony on the basis that it invades the province of the jury is more appropriately a question to be determined in this Court's discretion over the presentation of evidence at trial and not as part of this Court's gatekeeping function under *Daubert.*

Reliability of Mr. Bayley's Calculations

DePuy makes the argument that Mr. Bayley's calculations are unreliable because by Bayley's own admission there is no basis in accounting for considering dividends, materiality, or credit ratings for calculating the largest punitive damages award a company could sustain. Mr. Bayley, however, was not calculating an amount of punitive damages. He calculated Defendants' ability to pay—just one of the financial factors to be considered in awarding punitive damages. Mr. Bayley has ample expertise and experience in valuing businesses. His report explains in detail the methods he used and

the factors he considered in determining Defendants' ability to pay. He considered factors commonly used by anyone in analyzing the performance of a business and factors that were legally relevant under Montana law. Defendants do not dispute the accuracy or reliability of the underlying information Mr. Bayley used to make his calculations. The court in *In re Yasmin & YAZ (Drospirenone) Marketing, Sales Practices & Products Liability Litigation*, No. 09-02100, 2011 WL 6302287 at *7, n.7 (E.D. Ill. Dec. 16, 2011) determined that a financial expert's calculation of net worth of the defendant for purposes of awarding punitive damages based on reliable sources and methods generally accepted in the economic community was reliable. This Court finds that Bayley's methods are reliable as well.

C. The Expert Testimony of Rudolph Buchheit

Plaintiffs offer Rudolph G. Buchheit, Ph.D. as a designated expert on metal corrosion. Specifically, Plaintiffs seek to offer the opinion of Dr. Buchheit that the use of cobalt-chrome and titanium alloys in the design of the Pinnacle Device was destined to result in numerous damaging mechanisms of corrosion. In connection with this opinion, Dr. Buchheit offers several supporting opinions:

1. The mechanisms by which corrosion occurs (crevice effects, galvanic action, and fretting action) due to engineering design and materials selection.
2. The results of the corrosion (volume loss and wear debris generation) *in vivo*.
3. The high rate of incidence of corrosion on the Pinnacle articulating surfaces.

Dr. Buchheit bases his opinions on two different studies that he conducted on the Pinnacle Device for this MDL.

DePuy does not seem to challenge Dr. Buchheit's opinions but instead challenges the implications of the opinions. DePuy contends that Dr. Buchheit should not be allowed to testify as to any design or defect issues with respect to the Pinnacle Device or as to the cause of corrosion injuries to patients in general or to Ms. Lay and Ms. Paoli specifically because Dr. Buchheit is not qualified to do so and because his methodology is not reliable. DePuy contends that Dr. Buchheit's opinions should be limited to the proposition that cobalt-chrome and titanium alloys used in orthopedic implants may corrode.

Dr. Buchheit's Qualifications

Dr. Buccheit earned a Bachelor of Science degree in Engineering Science from Loyola University in Maryland and a Master of Science and Ph.D. in Materials Science from the University of Virginia. He currently serves as Chair of the Materials Science and Engineering Department at Ohio State University. His research and experience are in corrosion science and engineering with emphasis on the chemistry and electrochemistry of corrosion, corrosion metallurgy, localized corrosion, corrosion protection, and corrosion prediction. He has worked extensively in the area of corrosion inhibition, surface modification, and corrosion resistant coatings. He has published over 200 articles on these subjects. He holds eight patents related to surface treatments and

coating. He has edited, contributed to, and written numerous books on these subjects. He has been a member of or served on boards of various materials science, engineering, and corrosion organizations.

Dr. Buchheit is well qualified to give opinions relating to the causes and effects of corrosion of the Pinnacle Device, and that is what he has done in this case. His opinions are about the defects in the Pinnacle Device related to corrosion, the mechanisms by which corrosion occurs in the Pinnacle Device, the effects of the corrosion on the Pinnacle Device, and the high rate of incidence of corrosion in the Pinnacle Device. Dr. Buchheit has not opined about the defective design of the Pinnacle Device in general, and he has not offered an opinion about the effects of corrosion on the general population or on Plaintiffs in this case as DePuy alleges. DePuy's complaints about the implications of Dr. Buchheit's opinions are more appropriately raised at trial.

Reliability of Dr. Buchheit's Methodologies

DePuy suggests that two methodologies used by Dr. Buchheit in testing the Pinnacle Device are unrealiable—the pin-on-disk test and the explants study. In the pin-on-disk test, Dr. Buchheit used a Pinnacle Device to create a pin from the cobalt-chrome head and a disk from the titanium stem. He then used a tribometer to characterize the effect of fretting and free sliding on cobalt-chromium and titanium. The tribometer is described in peer-reviewed journal publications. Dr. Buchheit concluded from the results of the test that while cobalt-chromium and titanium are generally considered to be more

corrosion resistant than other metals, this passive character of these metals can be destroyed by fretting and free-sliding wear. DePuy argues that this test is unreliable because Dr. Buchheit stated that the test could not be used to predict the performance of a specific device. Instead Plaintiffs' contend that Dr. Buchheit opines that the mechanical action of the Pinnacle Device can affect the corrosion-resistant character of the metals used therein and that these results reliably show that cobalt-chromium and titanium can corrode at significantly higher rates compared to what is expected in the Pinnacle Device.

In his examination of explants, Dr. Buchheit inspected over 200 sets of metal-on-metal explanted Pinnacle Devices and ranked the extent of corrosion and wear on each one. He followed the methodology of a report published in 1993 by two doctors who have been designated as experts by DePuy and the standards for visual corrosion inspection promulgated by the American Society for Testing Materials. He concluded that the high rate of corrosion in these devices, mainly at the taper joint, is the result of a design defect because the Pinnacle Device was specifically designed to be corrosion resistant. This Court finds Dr. Buchheit's methodologies reliable—they were tested, subject to peer review and publication, and followed industry standards.

D. The Expert Testimony of Vicki L. Colvin

Plaintiffs designate Vicki L. Colvin, Ph.D. as an expert who opines that the metal-on-metal Pinnacle Device produces wear debris that includes cobalt nanoparticles which

cause cell death and physical injury and chromium which may cause systematic effects such as cancer. DePuy contends that Dr. Colvin's testimony regarding these matters is inadmissible because it is unreliable—it is not based on any science but is based on assumptions and speculation. Plaintiffs have represented that they do not intend to introduce in the *Lay* and *Paoli* cases any of Dr. Colvin's opinions on the systematic effects of wear debris, so this Court will address DePuy's motion with respect to the opinion that wear debris from the Pinnacle Device, including cobalt nanoparticles, may cause cell death and other physical injury.

DePuy's main complaint regarding reliability is that Dr. Colvin assumes that Pinnacle Devices release wear debris consisting of cobalt. It is undisputed that the Pinnacle Device is made of cobalt and chromium. DePuy contends that it is undisputed that wear debris from the Pinnacle Device consists of chromium but that there is no literature supporting Dr. Colvin's theory that the wear debris contains cobalt. Cobalt levels were tested and found to be elevated in Mrs. Lay and Mrs. Paoli. Dr. Colvin lists numerous studies in her report that found Pinnacle Devices produce cobalt nanoparticles. In addition, she points to two additional articles that were used to cross examine her in her deposition that support this finding. DePuy takes issue with Dr. Colvin's reliance on this literature claiming she did not take into account whether the implants were properly aligned and whether the particles under review were larger than nanoparticles. DePuy's criticism of Dr. Colvin's opinion is merely a battle of the experts

and goes to the weight rather than the admissibility of her testimony. A difference of opinion in interpreting the literature is not grounds for a *Daubert* challenge. *Kuhmo Tire Co., Ltd. v. Carmichael,* 526 U.S. 137, 153 (1999); *In re Chantix (Varenicline) Products Liability Litigation,* 889 F. Supp. 2d 1272, 1282-83 (N.D. Ala. 2012); *In re Vioxx Products Liability Litigation,* 401 F. Supp. 2d 565, 587 (E.D. La. 2005). Dr. Colvin's opinion that the Pinnacle Device releases wear debris containing cobalt is based on literature and is reliable.

DePuy additionally seeks to exclude Dr. Colvin's opinion as unreliable because she does not identify the amount of cobalt sufficient to cause damage and she cannot quantify the amount of Plaintiffs' exposure to cobalt. This is a localized injury to adjacent tissue, not an environmental exposure case. The precise amount of toxic cobalt is not necessary. *Sita v. Danek Medical, Inc.,* 43 F. Supp. 2d 245, 255 (E.D.N.Y. 1999); *In re Zicam Cold Remedy Marketing, Sales Practices, & Products Liability Litigation,* 797 F. Supp. 2d 940, 946-47 (D. Ariz. 2011). Dr. Colvin did, however, review both *in vitro* as well as *in vivo* studies and gave a range of the amount of toxic cobalt in her report. DePuy claims that Dr. Colvin cannot rely on *in vitro* studies because they cannot be extrapolated to the real world. This is no reason to exclude Dr. Colvin's testimony as unreliable under *Daubert. Zicam,* 797 F. Supp. 2d at 946-47.

And finally, DePuy attacks Dr. Colvin's "Trojan Horse" theory of cell death as unreliable because it has no basis in science. Dr. Colvin opines that cobalt nanoparticles

released in the wear debris of the Pinnacle Device dissolve in white blood cells that capture, process, and detoxify foreign bodies and are taken up to the acidic lysosomes of the cells. She opines that this process causes the cobalt nanoparticles to dissolve, releasing a toxic cargo that destroys the white blood cells before the nanoparticles are completely broken down. The cobalt particles then enter other white blood cells and repeat the cycle of cell death. Dr. Colvin describes cobalt's role in this process as the "Trojan Horse." Dr. Colvin relies on numerous studies and literature in forming her opinion, and her description of the process by which small particles destroy cells is generally accepted among the scientific community. Dr. Colvin employed expert analysis and scientific support for her opinions. DePuy's criticism of Dr. Colvin's opinion is again just a battle of the experts and goes to the weight rather than the admissibility of her testimony. A difference of opinion is not grounds for a *Daubert* challenge.

E. The Expert Testimony of Nicholas P. Jewell

Plaintiffs offer Dr. Jewell as a designated expert on biostatistics. Based on a review of certain data, Dr. Jewell opines that DePuy's claim that the Pinnacle Device has a 99.9% five-year survivorship rate is inaccurate and misleading. DePuy seeks to exclude this testimony, claiming Dr. Jewell based his opinions on the wrong data.

DePuy presented its five-year survivorship data in June of 2006. DePuy updated this report in October of 2006. DePuy used this updated October 2006 report for a poster presentation. It is this poster that Dr. Jewell contends contains inaccurate and

misleading claims about the 99.9% five-year survivorship rate of the Pinnacle Device. Dr. Jewell based his opinions on the June 2006 report mainly because at the time his report was due, DePuy had not produced the October 2006 report and he did not know of its existence. Dr. Jewell testified that whether he analyzed the June 2006 data or the October 2006 data, his opinion would be the same because there is very little difference between the two sets of data. In fact he verified this statement by using the data from the October 2006 report to recalculate his findings. Further, the factual basis for an expert's findings goes to the weight of his testimony not the admissibility. *See Pipitone v. Biomatrix, Inc.,* 288 F.3d 239, 250 (5th Cir. 2002). DePuy's attack on Dr. Jewell's opinion is not the proper subject of a *Daubert* motion.

F. Expert Testimony of John Ziegert

Plaintiffs proffer expert testimony from John C. Ziegert, Ph.D., an expert in measuring manufactured components. DePuy seeks to exclude one of Dr. Ziegert's opinions concerning the wear volume from Plaintiffs' explanted hip components. DePuy contends that Dr. Ziergert's is unqualified to offer an opinion on the wear volume of the hip components because he has not previously measured orthopedic components. In addition, DePuy alleges that Dr. Ziegert's opinion on wear volume is not reliable because there is no reliable way to measure wear volume in retrieved hip implants.

Dr. Ziegert's Qualifications

Dr. Ziegert is an expert in measuring manufactured components. He is a professor in the Department of Mechanical Engineering and Engineering Science at the University of North Carolina at Charlotte. He earned his B.S. in Mechanical Engineering, an M.S. in Theoretical & Applied Mechanics, and a Ph.D. in Mechanical Engineering. He has been president and vice president of the American Society for Precision Engineering and is editor-in-chief of *Precision Engineering.* He is a manuscript reviewer for numerous other publications in this field. He holds several patents, including a patent for a universal joint for a coordinate measuring machine. He has published dozens of articles in peer-reviewed journals in the field of mechanical engineering and the area of measurement. He is an expert in metrology, the science of measurement.

DePuy argues that Dr. Ziegert is not qualified because he is not an expert in friction and wear; but, he does not need to be. He is an expert in measurement, and he measured the volume of material that was worn away from the Pinnacle Devices that had been implanted in Ms. Lay and Ms. Paoli. The question of how the devices were worn has nothing to do with measurement of the amount of wear. DePuy further argues that Dr. Ziergert is unqualified because he has never before measured orthopedic devices. This Court does not see how measuring a sphere in a medical device is any different from measuring a sphere in any other manufactured component for which Dr. Ziergert is amply qualified. Along this same argument, DePuy contends that Ziegert is unqualified

because he had never used the ASTM Draft Standard Guide (a guide for measuring wear in hip devices) or GeoMagic software before measuring the Pinnacle Devices and he had never calculated the uncertainty of measurements produced by GeoMagic software. Dr. Ziegert testified that he had used software similar to GeoMagic. Dr. Ziegert has calculated the uncertainty of measurements of all types including the one in this case. DePuy's arguments are more appropriate for cross examination at trial.

DePuy argues that Dr. Ziegert is unqualified because no other peer-reviewed article he relied on used the GeoMagic software or the specific method he followed. The Court interprets this argument as an attack on the reliability of Dr. Ziegert's opinions instead of his qualifications. Whether based on qualifications or reliability, the argument still fails. Dr. Ziegert used his expertise in measuring to select the software that in his opinion would be best suited for this measurement. The GeoMagic software and Dr. Ziegert's methods have been reported in peer-reviewed articles and have been the subject of published papers. DePuy's disagreement about how Dr. Ziegert executed the steps in the process for measuring wear volume goes to the weight not the admissibility of this testimony. *See Wattle v. Barko Hydraulics LLC,* 107 Fed. Appx. 396, 398 (5th Cir. 2004).

Reliability of Dr. Ziegert's Methodologies

DePuy claims that Dr. Ziegert's methodologies are unreliable because they are not generally accepted. As discussed above, general acceptance is no longer the standard for admissibility of expert testimony. General acceptance might still have a role to play in

assessing expert testimony, but it is a minor role and need not be present for expert testimony to be admissible. *Daubert,* 509 U.S. at 594. But in this case, the methods for measuring wear volume have experienced some acceptance. The ASTM Draft Standard Guide is evidence of this acceptance. DePuy has hired a consultant to compute wear volumes who has testified that the ASTM Draft Standard Guide is sufficient for measuring wear on explanted Pinnacle Devices. There are also several papers that set out similar testing methods.

DePuy finally argues that Dr. Ziegert's methodologies are not reliable because they have not been peer-reviewed or subjected to testing and have no known rate of error. Dr. Ziegert used the ASTM guidelines and well as three different published papers that have been peer-reviewed and tested and his own expertise. Further, Dr. Ziegert reports his findings with uncertainty factors. This is a known rate of error. This Court finds Dr. Ziegert's methodologies sufficiently reliable. To the extent DePuy is arguing that Dr. Ziegert did not follow the ASTM standards or that his calculations are incorrect, such argument goes to the weight and not the admissibility of the evidence.

IV. CONCLUSION

In its motions to exclude expert testimony, DePuy has attacked and pointed out numerous weaknesses in the PEC's proffered expert testimony. This does not, however, make the expert testimony inadmissible under rule 702 or invoke this Court's gate-keeping authority under *Daubert*. DePuy has made no credible argument that any of the

Plaintiffs' expert testimony is being offered by unqualified experts or is unreliable or irrelevant. DePuy's arguments against admissibility are more appropriately raised at trial in motions in limine and objections and through vigorous cross examination of the experts, presentation of contrary evidence, and this Court's careful instruction on the burden of proof. For the reasons stated herein, DePuy's motions to exclude the expert testimony of John Abramson, M.D., Scott Bayley, C.P.A., Rudolph Buchheit, Ph.D., Vicki Colvin, Ph.D., Nicholas Jewell, Ph.D., and John Ziegert, Ph.D. are **DENIED.**

SO ORDERED.

Signed July 18, 2014.

Ed Kinkeade

ED KINKEADE
UNITED STATES DISTRICT JUDGE